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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,027	07/16/2003	Evan C. Unger	5030-0003.01	1650

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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,027	UNGER, EVAN C.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-20,23-38,41,42 and 44-53* is/are pending in the application.

4a) Of the above claim(s) *11,12,16-18,26,27 and 29-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10,13-15,19-20,23-25,28,41-42,44-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments to the claims filed 02/27/2007 have been entered. Any objection/rejection from the previous office action dated 11/28/2006 not addressed herein have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,6-10,13-15,19-20,23-25,28,41-42,44-50,52 are rejected under 35 U.S.C. 102(e) as being anticipated by Unger et al. (US 5,542,935). This new ground of rejection was necessitated by amendment.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Unger teaches therapeutic delivery systems comprising a gaseous precursor (including perfluoropropane) filled microspheres, surfactants including polysorbate 80, a therapeutic including taxol and stabilizers including PEG, especially PEG with a MW of 400. See col 17 lin 17-20, col 23 lin 10-lin 38, col 24 lin 33, col 29 lin 11-20 and col 49

lin 25-col 50 lin 33. Regarding claim 3 the limitation that the therapeutic composition is further rehydrated with aqueous solution is considered met because Unger teaches that the therapeutic systems of the invention are administered in the form of an aqueous suspension, after the gas installation method is performed on the dried liposomes it is inherent that the composition must be rehydrated in order be administered as an aqueous solution. See col 31 lin 29-35 and col 48 lin 1-col 50 lin 59. Regarding claims 19 and 20 which are product by process claims "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding claim 28, Unger states that size of the microspheres depend upon their intended use, and further states that in intravascular applications the preferred size range is between about 30 nm and about 10 microns, within applicants claimed range. See col 30 lin 58-lin 67.

Claim Rejections - 35 USC § 103

Claims 1-4,6-10,13-15,19-20,23-25,28,41-42 and 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. (US 5,542,935) in view of Kabalnov et al. (US 5,804,162). This new ground of rejection was necessitated by amendment.

Unger is disclosed above. Unger while disclosing perfluorocarbons as useful gasses in the disclosed therapeutic systems comprising a contrast agent or drug, the patent does not disclose the use of fluorinated ethers as the gaseous precursor.

Kabalnov is used only for the disclosure within that perfluoroethers were already well known in the art at the time of the invention to be useful in gas filled contrast enhancing compositions. See abstract, col 8 lin 20-48 and col 9 lin 53-col 11 lin 29.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the perfluorocarbon gasses disclosed in Unger and add the perfluoroether gas disclosed within Kabalnov. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of perfluorocarbon gas filled contrast agents. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claims 1-4,6-10,13-15,19-20,23-25,28,41-42 and 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. (US 5,469,854, disclosed in previous office action, '854 from hereon) in view of Unger et al. (WO 94/28780 A2, '780 from hereon) in view of Kabalnov et al. (US 5,804,162). This new ground of rejection was necessitated by amendment.

'854 discloses a method of preparing gas filled liposomes, which are disclosed as useful in ultrasonic imaging and therapeutic drug delivery. See abstract. The liposomes can be stored in the dry state and then resuspended latter in a liquid medium, the drying could be achieved by lyphilization. See col 3 lin 33-50, col 6 lin 8-24 and examples. The therapeutic compositions in '854 comprise other additional ingredients such as emulsifiers, suspending and or/viscosity modifiers including polyethylene oxide and polysorbate-80. See col 13 lin 25-54, col 15 lin 31-39. '854 also discloses a broad range of actives that can be used in therapeutic drug delivery including Taxol. See col 22 lin 9-12. Regarding claims 19 and 20 which are product by process claims "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding the limitation in claim 10 that the additive is PEG-400 it would have been obvious to the skilled artisan that PEG-400 could be selected among the disclosed viscosity modifiers because '854 discloses that the viscosity modifiers such as polyethers should contain a MW between 400 and 8000, therefore PEG-400 is obviously one of the polyethers encompassed within this broad range (polyethylene oxide and PEG are the same polyether). See col 13 lin 25-53.

'854 while disclosing gas filled liposomes is silent on the use of the exact gasses perfluorocarbon, perfluoroether and sulfur hexafluoride as now claimed by applicants.

'780 discloses gas filled and gaseous precursor filled microspheres useful in imaging applications and in therapeutic drug delivery systems comprising a gaseous precursor (including perfluoropropane) filled microspheres, surfactants including polysorbate 80, a therapeutic including taxol and stabilizers including PEG. See abstract, pag 35 lin 15, pag 42 lin 11,19, 35 and pag 61 lin 11.

Kabalnov is used only for the disclosure within that perfluoroethers were already well known in the art at the time of the invention to be useful in gas filled contrast enhancing compositions. See abstract, col 8 lin 20-48 and col 9 lin 53-col 11 lin 29.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the gasses disclosed in '854 and add the perfluorocarbon gasses of '780 and the perfluoroether gases disclosed within Kabalnov. It is generally considered to be prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of gas filled contrast agents. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER